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RICHARD W. WIEKING
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NORTHERN DISTRICT OF CALIFORNIA

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

CRB

EDNA BURNETTE, (NC)

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION
and G.D. SEARLE, LLC,

Defendants.

C 07 2690

CIVIL COMPLAINT

JURY TRIAL DEMANDED

Plaintiff EDNA BURNETTE, by and through her counsel, bring this action against Defendants PFIZER, INC., PHARMACIA CORP., and G.D. SEARLE & CO. (hereinafter collectively "Defendants") and allege as follows:

I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe medication Valdecobix, trade name BEXTRA® ("BEXTRA").

2. Plaintiff EDNA BURNETTE was at all relevant times adult resident citizens of the State of North Carolina, County of Onslow. Plaintiff EDNA BURNETTE began ingesting Bextra on

COMPLAINT

1 or about May 15, 2004. As a direct and proximate result of ingesting BEXTRA, Plaintiff suffered a
2 Stroke on May 30, 2004 resulting in hospitalization, and on June 1, 2004, the Plaintiff suffered a Deep
3 Vein Thrombosis resulting in hospitalization, which has caused and will continue to cause Plaintiff
4 damages and places Plaintiff at risk of further serious injury or death.

5 3. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of
6 business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly
7 \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the
8 business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and
9 selling the drug Valdecobix, under the trade name BEXTRA in California and nationwide.

10 4. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. ("Searle") is a
11 Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has
12 been engaged in the business of marketing and selling BEXTRA nationwide and in California. Searle
13 is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this Complaint.

14 5. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its
15 principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors in
16 interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing,
17 distributing, promoting, and selling BEXTRA nationwide and in California.

18 **II. JURISDICTION AND VENUE**

19 6. This is an action for damages, which exceeds seventy-five thousand dollars
20 (\$75,000.00).

21 7. There is complete diversity of citizenship between the Plaintiff and Defendants. This
22 Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity
23 jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there is complete
24 diversity of citizenship between Plaintiff and Defendants.

25 8. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A. § 1391.
26 Defendants marketed, advertised and distributed the dangerous product in the district, thereby
27 receiving substantial financial benefit and profits the dangerous product in this district, and reside in
28 this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

9. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, BEXTRA. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including California and Louisiana) the aforementioned prescription drug. Defendants do substantial business in the State of California and within this Federal Judicial District, advertise in this district, receive substantial compensation and profits from sales of BEXTRA in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the agent for each of the other defendants, or those defendant's predecessors in interest.

III. INTERDISTRICT ASSIGNMENT

10. Assignment to the San Francisco Division is proper as this action is related to *In Re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

IV. FACTUAL BACKGROUND

A. Facts Regarding Plaintiff

11. Plaintiff and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries unaware - and could not have reasonably known or have learned through reasonable diligence - that such injury directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from Plaintiffs' ingestion of BEXTRA.

12. Plaintiff used BEXTRA in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

13. Plaintiff would not have used BEXTRA had Defendants properly disclosed the risks associated with the drug.

B. Facts Regarding Bextra and Bextra's Market Launch

14. Bextra is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are

1 examples of well-known NSAIDs.

2 15. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes
3 called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2.

4 Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

5 16. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1
6 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the
7 hydrochloric acid present in the stomach. It is generally accepted in the medical community that by
8 blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result,
9 can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

10 17. Prostaglandin I₂ is the predominant cyclooxygenase product in endothelium, inhibiting
11 platelet aggregation (preventing clot formation), causing vasodilation, and preventing the proliferation
12 of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A₂ and Prostaglandin I₂,
13 the COX-2 inhibitors leave Thromboxane A₂ unaffected. Thromboxane A₂ is a potent platelet
14 aggregator and vasoconstrictor, which is synthesized by platelets. Therefore, while the older NSAIDS
15 suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

16 18. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by
17 inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional
18 NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots,
19 rather they actually reduce the risk of clots and help protect heart function.

20 19. Defendants and other pharmaceutical companies set out to remedy these ulcer and
21 bleeding problems suffered by some NSAID users by developing "selective" inhibitors that would
22 block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue
23 while still reducing inflammation.

24 20. In making this decision, Defendants and their predecessors in interest either
25 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
26 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
27 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,
28 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

21. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

22. Seeking increased market share in this extremely lucrative market, Defendants, and their predecessors in interest, also sought approval of a “second generation” selective COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

23. The FDA granted approval of the new drug on November 16, 2001, for two particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

24. The FDA did not grant approval to market and promote Bextra for the management or prevention of acute pain.

25. The FDA did not grant approval to promote Bextra as more effective than other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers or gastric bleeding.

26. Even without a label that allowed Defendants to legitimately claim superior safety, when Defendants, and their predecessors-in-interest, began marketing Bextra in early 2002, Defendants and their representatives and agents misrepresented the safety profile of Bextra to consumers, including Plaintiff, the medical community, healthcare providers, and third party payers.

27. Defendants proceeded to promote, market, sell, and distribute Bextra as a much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

C. Facts Regarding Bextra’s Safety and Defendants’ Knowledge Thereof.

28. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in November 2, 2001. By 1997, and prior to the submission of the New Drug Application (the “NDA”) for Bextra, Defendants were aware that, by inhibiting COX-2, Bextra altered the homeostatic balance between prostacyclin synthesis and

1 thromboxane and thereby, increased the prothrombotic effects of the drugs, causing blood clots to
2 form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with*
3 *Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954. Although all COX-2 inhibitors have this
4 mechanism of action, Bextra was the most selective COX-2 inhibitor proposed for approval.
5 Accordingly, it had the greatest potential to cause adverse cardiovascular and cerebrovascular events.

6 29. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported
7 in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it was
8 known as early as 1999 that selective COX-2 inhibitors, such as Bextra, suppressed the formation of
9 prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose
10 patients to myocardial infarction or thrombotic stroke.

11 30. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the FDA for
12 Bextra, omitting information about the extent of the risks associated with Bextra. Without a complete
13 picture of the potential hazards associated with the drug, the FDA approved Bextra on or about
14 November 16, 2001.

15 31. Based on the studies performed on Celebrex, Vioxx, Bextra, and other COX-2
16 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted,
17 Defendants knew when Bextra was being developed and tested that selective COX-2 inhibitors posed
18 serious cardiovascular risks for anyone who took them, and presented a specific additional threat to
19 anyone with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2
20 inhibitors, including Bextra, decrease blood levels of a prostacyclin. When those levels fall, the
21 arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

22 32. On December 9, 2004, the FDA issued new information on side effects associated with
23 the use of Bextra and required the addition of certain warnings to, and the strengthening of other
24 warnings on, the Bextra label. The enhanced warnings followed in the wake of the results of
25 additional cardiovascular studies performed by Defendants, as well as numerous complaints to the
26 FDA regarding severe skin reactions.

27 33. Yet well prior to this warning, Defendants had knowledge of the coronary and
28 cardiovascular safety risks of Bextra from several studies. *See e.g.*, Otto, E.O., *Efficacy and Safety of*

1 *the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery*
2 *Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery*, June 2003 at 1481.

3 34. Even Defendants' own (and Pfizer funded) post- drug approval meta-analysis study
4 (first presented on March 31, 2003 and again on May 15, 2003) included this data showing an
5 increased cardiovascular risk in patients treated with Bextra after undergoing coronary artery bypass
6 graft surgery. Observed events included heart attack, stroke, and blood clots in the legs and lungs.
7 The results were particularly relevant and striking as each of the study participants who were a post-
8 bypass surgery patient was taking anti-clotting agents at the time their exposure to Bextra was being
9 tracked.

10 35. In mid-January 2005, a peer-reviewed paper from the University of Pennsylvania found
11 that in patients having heart bypass surgery, those who took Bextra in the intravenous form, parecoxib,
12 as opposed to a placebo, were three times more likely to have a heart attack or stroke.

13 36. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory
14 Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of
15 COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham testified that selective
16 COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette
17 smoking, hypertension, and diabetes.

18 37. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new
19 studies specifically analyzing the risks of Bextra, Defendants failed to take any action to protect the
20 health and welfare of patients, but instead, continued to promote the drug for sale even after the FDA's
21 Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee
22 meetings.

23 38. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily withdraw"
24 Bextra from the U.S. market, stating:

25 " . . . the Agency has concluded that the overall risk versus
26 benefit profile of Bextra is unfavorable. This conclusion is based on the
27 potential increased risk for serious cardiovascular (CV) adverse events,
28 which appears to be a class effect of non-steroidal anti-inflammatory
drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin
reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome,
erythema multiforme) compared to other NSAIDs, and the fact that

1 Bextra has not been shown to offer any unique advantage over the other
2 available NSAIDs.”

3 39. FDA Alert for Healthcare Professionals, April 7, 2005.

4 Continuing, the FDA noted:

5 “Bextra has been demonstrated to be associated with an
6 increased risk of serious adverse CV events in two short-term trials in
7 patients immediately post-operative from coronary artery bypass graft
8 (CABG) surgery FDA has concluded that it is reasonable to
9 extrapolate the adverse CV risk information for Bextra from the short-
10 term CABG trials to chronic use given the fact that other COX-2
11 selective NSAIDs have been shown in long-term controlled clinical
12 trials to be associated with an increased risk of serious adverse CV
13 events (e.g., death, MI, stroke), and the well described risk of serious,
14 and often life-threatening gastrointestinal bleeding To date, there
15 have been no studies that demonstrate an advantage of Bextra over other
16 NSAIDs that might offset the concern about the[] serous skin risks, such
17 as studies that show a GI safety benefit, better efficacy compared to
18 other products, or efficacy in a setting of patients who are refractory to
19 treatment with other products.”

20 40. The scientific data available during and after Bextra’s approval process made clear to
21 Defendants that their formulation of Bextra would cause a higher risk of blood clots, stroke and/or
22 myocardial infarctions among Bextra consumers, alerting them to the need to do additional and
23 adequate safety studies.

24 41. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*,
25 outlining Defendants’ failure to have conducted the necessary trials before marketing to humans
26 “. . . it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2
27 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease,
28 who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further
cardiovascular events.”

42. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed
above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2
inhibitors.

43. Based upon readily available scientific data, Defendants knew, or should have known,
that their pre-approval testing of Bextra did not adequately represent the cross-section of individuals
who were intended consumers and therefore, likely to take Bextra. Therefore, Defendants’ testing and

1 studies were grossly inadequate. *See, e.g.*, PDR entry for Bextra (noting that: “**Platelets:** In four
2 clinical studies with young and elderly (≥ 65 years) subjects, single and multiple doses up to 7 day
3 mg BID had no effect on platelet aggregation”).

4 44. Had Defendants done adequate testing prior to approval and “market launch,” rather
5 than the extremely short duration studies done on the small size patient base that was actually done,
6 Pharmacia and Searle’s scientific data would have revealed significant increases in incidence of
7 strokes and myocardial infarctions among the intended and targeted population of Bextra consumers.
8 Adequate testing would have shown that Bextra possessed serious side effects for individuals such as
9 Plaintiff. Defendants should have taken appropriate measures to ensure that their defectively designed
10 product would not be placed in the stream of commerce and/or should have provided full and proper
11 warnings accurately and fully reflecting the scope and severity of symptoms of those side effects
12 should have been made.

13 45. In fact, post-market approval data did reveal increased risks of clotting, stroke and
14 myocardial infarction, but this information was intentionally suppressed by Defendants in order for
15 them to gain significant profits from continued Bextra sales.

16 46. Defendants’ failure to conduct adequate testing and/or additional testing prior to
17 “market launch” was based upon their desire to generate maximum financial gains for themselves and
18 to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

19 47. At the time Defendants manufactured, advertised, and distributed Bextra to consumers,
20 Defendants intentionally or recklessly ignored and/or withheld information regarding the increased
21 risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such
22 increased risks were disclosed, consumers such as Plaintiffs would not purchase Bextra, but instead
23 would purchase other cheaper and safer NSAIDs.

24 **D. Facts Regarding Defendants’ Marketing and Sale of Bextra**

25 48. Plaintiff at all times relevant herein, Defendants engaged in a marketing campaign with
26 the intent that consumers would perceive Bextra as a safer and better drug than its other NSAIDs and,
27 therefore, purchase Bextra.

28 49. Defendants widely and successfully marketed Bextra throughout the United States by,

1 among other things, conducting promotional campaigns that misrepresented the efficacy of Bextra in
2 order to induce a widespread use and consumption. Bextra was represented to aid the pain and
3 discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by
4 means of media advertisements, and statements contained in sales literature provided to Plaintiff's
5 prescribing physicians.

6 50. Despite knowledge of the dangers presented by Bextra, Defendants and Defendants'
7 predecessors in interest, through their officers, directors and managing agents for the purpose of
8 increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known
9 defects of Defendants' product, Bextra, and failed to warn the public, including Plaintiff, of the serious
10 risk of injury occasioned by the defects inherent in Defendants' product, Bextra. Defendants and their
11 officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the
12 manufacturing, sale and marketing of Defendants' product, Bextra, knowing that persons would be
13 exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants'
14 conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and
15 particularly of Plaintiff.

16 51. In an elaborate and sophisticated manner, Defendants aggressively marketed Bextra
17 directly to consumers and medical professionals (including physicians and leading medical scholars) in
18 order to leverage pressure on third party payers, medical care organizations, and large institutional
19 buyers (*e.g.*, hospitals) to include Bextra on their formularies. Faced with the increased demand for
20 the drug by consumers and health care professionals that resulted from Defendants' successful
21 advertising and marketing blitz, third party payers were compelled to add Bextra to their formularies.
22 Defendants' marketing campaign specifically targeted third party payers, physicians, and consumers,
23 and was designed to convince them of both the therapeutic and economic value of Bextra.

24 52. Defendants represented that Bextra was similar to ibuprofen and naproxen but was
25 superior because it lacked any of the common gastrointestinal adverse side effects associated with
26 these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance, NSAIDS can, in
27 certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use.
28 Defendants promoted Bextra as a safe and effective alternative that would not have the same

1 deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain
2 relief.

3 53. Bextra possessed dangerous and concealed or undisclosed side effects, including the
4 increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting,
5 deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, Bextra
6 was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs,
7 carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants chose not to warn
8 about these risks and dangers.

9 54. Defendants knew of these risks before the U.S. Food and Drug Administration (the
10 “FDA”) approved Bextra for sale on November 16, 2001, but Defendants ignored, downplayed,
11 suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion,
12 advertising, marketing, and sale of Bextra. Defendants’ omission, suppression, and concealment of
13 this important information enabled Bextra to be sold to, and purchased, or paid for by, the consumers
14 at a grossly inflated price.

15 55. Consequently, Bextra captured a large market share of anti-inflammatory drugs
16 prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002), sales of
17 Bextra exceeded \$1.5 billion, despite the significantly higher cost of Bextra as compared to other pain
18 relievers in the same family of drugs.

19 56. It was not until April 7, 2005, that Defendants finally acknowledged Bextra’s
20 deleterious side effects and announced that they were withdrawing the drug from the worldwide
21 market based on what it misleadingly termed “new” and “unexpected” evidence linking Bextra to an
22 increased risk of heart attacks and strokes.

23 57. Had Defendants done adequate testing prior to approval and “market launch,”
24 Pharmacia’s scientific data would have revealed significant increases in stroke and myocardial
25 infarction amongst the intended population of BEXTRA consumers. Adequate testing would have
26 shown that BEXTRA possessed serious side effects. Defendants should have taken appropriate
27 measures to ensure that their defectively designed product would not be placed in the stream of
28 commerce and/or should have provided full and proper warnings accurately and fully reflecting the

1 scope and severity of symptoms of those side effects should have been made.

2 58. In fact, post-market approval data did reveal increased risks of clotting, stroke and
3 myocardial infarction, but this information was intentionally suppressed by Defendants in order for
4 them to gain significant profits from continued BEXTRA sales.

5 59. Defendants' failure to conduct adequate testing and/or additional testing prior to
6 "market launch" was based upon their desire to generate maximum financial gains for themselves and
7 to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

8 60. At the time Defendants manufactured, advertising, and distributed BEXTRA to
9 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the
10 increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if
11 such increased risks were disclosed, consumers such as Plaintiffs would not purchase BEXTRA, but
12 instead would purchase other cheaper and safer NSAID drugs.

13 61. At all times relevant herein, Defendants engaged in a marketing campaign with the
14 intent that consumers, including Plaintiff, and their doctors would perceive BEXTRA as a better drug
15 than its competitors and, therefore, purchase BEXTRA.

16 62. Defendants widely and successfully marketed BEXTRA throughout the United States
17 by, among other things, conducting promotional campaigns that misrepresented the efficacy of
18 BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the
19 pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made
20 misrepresentations by means of media advertisements, and statements contained in sales literature
21 provided to Plaintiff's prescribing physicians.

22 63. Prior to manufacturing, sale and distribution of BEXTRA, Defendants, through their
23 officers, director and managing agents, had notice and knowledge from several sources, that BEXTRA
24 presented substantial and unreasonable risks of harm to the consumer. As such, BEXTRA consumers,
25 including Plaintiff, were unreasonably subject to risk of injury or death from the consumption of
26 Defendants' product, BEXTRA.

27 64. Despite such knowledge, Defendants and Defendants' predecessors in interest, through
28 their officers, directors and managing agents for the purpose of increasing sales and enhancing its

1 profits, knowingly and deliberately failed to remedy the known defects of Defendants' product,
2 BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by
3 the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and
4 managers intentionally proceeded with the inadequate testing, and then the manufacturing, sale and
5 marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious
6 potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton
7 and willful, and displayed a conscious disregard for the safety of the public and particularly of
8 Plaintiff.

9 **CLAIMS FOR RELIEF**

10 **FIRST CLAIM FOR RELIEF**

11 **Negligence**

12 65. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully
13 set forth herein and further allege as follows.

14 66. Defendants owed Plaintiff a duty to exercise reasonable care when designing,
15 manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty included the
16 duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of commerce that
17 caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

18 67. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff
19 and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug BEXTRA.

20 68. Defendants breached their duties by failing to exercise ordinary care in the preparation,
21 design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion,
22 advertising and selling of BEXTRA, including: failing to use due care in the preparation and
23 development of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs
24 were ingested;

25 a. failing to use due care in the design of BEXTRA to prevent the aforementioned
26 risk of injuries to individuals when the drugs were ingested;

27 b. failing to conduct adequate pre-clinical testing and research to determine the
28 safety of BEXTRA;

1 c. failing to conduct adequate post-marketing surveillance and exposure studies to
2 determine the safety of BEXTRA;

3 d. failing to completely, accurately and in a timely fashion, disclose the results of
4 the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the
5 medical community, and the FDA;

6 e. failing to accompany BEXTRA with proper warnings regarding all possible
7 adverse side effects associated with the use of BEXTRA;

8 f. failing to use due care in the manufacture, inspection, and labeling of BEXTRA
9 to prevent the aforementioned risk of injuries to individuals who used BEXTRA;

10 g. failing to use due care in the promotion of BEXTRA to prevent the
11 aforementioned risk of injuries to individuals when the drugs were ingested;

12 h. failing to use due care in the sale and marketing of BEXTRA to prevent the
13 aforementioned risk of injuries to individuals when the drugs were ingested;

14 i. failing to use due care in the selling of BEXTRA to prevent the aforementioned
15 risk of injuries to individuals when the drugs were ingested;

16 j. failing to provide adequate and accurate training and information to the sales
17 representatives who sold BEXTRA;

18 k. failing to provide adequate and accurate training and information to healthcare
19 providers for the appropriate use of BEXTRA; and

20 l. being otherwise reckless, careless and/or negligent.

21 69. Despite the fact that Defendants knew or should have known that BEXTRA caused
22 unreasonable and dangerous side effects which many users would be unable to remedy by any means,
23 Defendants continued to promote and market BEXTRA to consumers, including Plaintiff, when safer
24 and more effective methods of pain relief were available.

25 70. Defendants were, or should have been, had they exercised reasonable care, in
26 possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless, they
27 continued to market their products by providing false and misleading information with regard to the
28 safety and efficacy of BEXTRA.

1 71. Defendants knew or should have known that consumers such as Plaintiffs would
2 foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

3 72. As a direct and proximate consequence of Defendants' acts, omissions, and
4 misrepresentations described herein, Plaintiff sustained serious injuries and related losses. Plaintiff
5 required and will continue to require healthcare and services. Plaintiff has incurred and will continue
6 to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer mental
7 anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished
8 quality of life, increased risk of premature death, aggravation of preexisting conditions and activation
9 of latent conditions, and other losses and damages. Plaintiff also incurred direct medical losses and
10 costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
11 Plaintiff has also suffered loss of wages.

12 73. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
13 deliberate disregard for the value of human life and the rights and safety of consumers, including
14 Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and
15 deter them from similar conduct in the future.

16 74. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory
17 damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys'
18 fees and such other and further relief as this Court deems just and proper.

19 **SECOND CLAIM FOR RELIEF**

20 **Strict Liability**

21 75. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully
22 set forth herein and further allege as follows.

23 76. At all times relevant to this action, Defendants were suppliers of BEXTRA, placing the
24 drug into the stream of commerce. BEXTRA was expected to and did reach Plaintiff without
25 substantial change in the condition in which it was manufactured and sold.

26 77. BEXTRA was unsafe for normal or reasonably anticipated use.

27 78. BEXTRA was defective in design or formulation because when it left the hands of the
28 manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary

1 consumer would expect. BEXTRA was also defective and unreasonably dangerous in that the
2 foreseeable risk of injuries from BEXTRA exceeded the benefits associated with the design and/or
3 formulation of the product.

4 79. Bextra is unreasonably dangerous: a) in construction or composition as provided in R.S.
5 9:2800.55; b) in design as provided in R.S. 9:2800.56; c) because an adequate warning about the
6 product was not provided as required by R.S. 9:2800.57; d) because it does not conform to an express
7 warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

8 80. The characteristics of Bextra that render it unreasonably dangerous under R.S.
9 9:2800.55, et seq., existed at the time the product left the control of the manufacturer or resulted from
10 a reasonably anticipated alteration or modification of the product.

11 81. The BEXTRA manufactured and supplied by Defendants was also defective due to
12 inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting
13 regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate
14 testing before exposing Plaintiff to the medication, testing which would have shown that BEXTRA
15 had the potential to cause serious side effects including strokes like that which affected Plaintiff.

16 82. The BEXTRA manufactured and supplied by Defendants was defective due to
17 inadequate post-marketing warnings or instructions because, after Defendants knew or should have
18 known of the risk of injuries from BEXTRA, they failed to provide adequate warnings to the medical
19 community and the consumers, to whom they were directly marketing and advertising BEXTRA; and,
20 further, it continued to affirmatively promote BEXTRA as safe and effective.

21 83. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised and
22 promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective
23 design of BEXTRA, Plaintiff used BEXTRA rather than other safer and cheaper NSAIDs. As a result,
24 Plaintiff suffered the personal injuries described above.

25 84. Information given by Defendants to the medical community and to the consumers
26 concerning the safety and efficacy of BEXTRA, especially the information contained in the
27 advertising and promotional materials, did not accurately reflect the potential side effects of BEXTRA.

28 85. Had adequate warnings and instructions been provided, Plaintiff would not have taken

1 BEXTRA as they did, and would not have been at risk of the harmful side effects described herein.

2 86. Defendants acted with conscious and deliberate disregard of the foreseeable harm
3 caused by BEXTRA.

4 87. Plaintiff could not, through the exercise of reasonable care, have discovered
5 BEXTRA's defects or perceived the dangers posed by the drug.

6 88. As a direct and proximate consequence of Defendants' acts, omissions, and
7 misrepresentations described herein, Plaintiff sustained serious injuries and related losses. Plaintiff
8 required and will continue to require healthcare and services. Plaintiff has incurred and will continue
9 to incur medical and related expenses. Plaintiff also have suffered and will continue to suffer mental
10 anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished
11 quality of life, increased risk of premature death, aggravation of preexisting conditions and activation
12 of latent conditions, and other losses and damages. Plaintiff also incurred direct medical losses and
13 costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
14 Plaintiff has also suffered loss of wages.

15 89. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
16 deliberate disregard for the value of human life and the rights and safety of consumers, including
17 Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and
18 deter them from similar conduct in the future.

19 90. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory
20 damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys'
21 fees and such other and further relief as this Court deems just and proper.

22 **THIRD CLAIM FOR RELIEF**

23 **Breach of Express Warranty**

24 91. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully
25 set forth herein and further allege as follows.

26 92. Defendants expressly represented to Plaintiff and other consumers and the medical
27 community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable
28 quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects,

1 and that it was adequately tested.

2 93. These warranties came in the form of:

3 a. Defendants' public written and verbal assurances of the safety and efficacy of
4 BEXTRA;

5 b. Press releases, interviews and dissemination via the media of promotional
6 information, the sole purpose of which was to create an increased demand for BEXTRA, which failed
7 to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term
8 ingestion of BEXTRA;

9 c. Verbal and written assurances made by Defendants regarding BEXTRA and
10 downplaying the risk of injuries associated with the drug;

11 d. False and misleading written information, supplied by Defendants, and
12 published in the Physician's Desk Reference on an annual basis, upon which physicians relied in
13 prescribing BEXTRA during the period of Plaintiffs' ingestion of BEXTRA, and;

14 e. advertisements.

15 94. The documents referred to above were created by and at the direction of Defendants.

16 95. Defendants knew or had reason to know that BEXTRA did not conform to these
17 express representations in that BEXTRA is neither as safe nor as effective as represented, and that
18 BEXTRA produces serious adverse side effects.

19 96. BEXTRA did not and does not conform to Defendants' express representations because
20 it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes
21 severe and permanent injuries.

22 97. Plaintiff, other consumers, and the medical community relied upon Defendants' express
23 warranties.

24 98. As a direct and proximate consequence of Defendants' acts, omissions, and
25 misrepresentations described herein, Plaintiff sustained serious injuries and related losses. Plaintiff
26 required and will continue to require healthcare and services. Plaintiff has incurred and will continue
27 to incur medical and related expenses. Plaintiff also have suffered and will continue to suffer mental
28 anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished

1 quality of life, increased risk of premature death, aggravation of preexisting conditions and activation
2 of latent conditions, and other losses and damages. Plaintiff also incurred direct medical losses and
3 costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
4 Plaintiff has also suffered loss of wages.

5 99. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
6 deliberate disregard for the value of human life and the rights and safety of consumers, including
7 Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and
8 deter them from similar conduct in the future.

9 100. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory
10 damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys'
11 fees and such other and further relief as this Court deems just and proper.

12 **FOURTH CLAIM FOR RELIEF**

13 **Breach of Implied Warranty**

14 101. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully
15 set forth herein and further allege as follows.

16 102. Defendants manufactured, distributed, advertised, promoted, and sold BEXTRA.

17 103. At all relevant times, Defendants knew of the use for which BEXTRA was intended
18 and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

19 104. Defendants were aware that consumers, including Plaintiff, would use BEXTRA for
20 treatment of pain and inflammation and for other purposes.

21 105. Plaintiff and the medical community reasonably relied upon Defendants' judgment and
22 expertise to only sell them or allow them to prescribe BEXTRA only if it was indeed of merchantable
23 quality and safe and fit for its intended use. Consumers, including Plaintiff, and the medical
24 community, reasonably relied upon Defendants' implied warranty for BEXTRA.

25 106. BEXTRA reached consumers, including Plaintiff, without substantial change in the
26 condition in which it was manufactured and sold by Defendants.

27 107. Defendants breached their implied warranty to consumers, including Plaintiff;
28 BEXTRA was not of merchantable quality or safe and fit for its intended use.

1 108. As a direct and proximate consequence of Defendants' acts, omissions, and
2 misrepresentations described herein, Plaintiff sustained serious injuries and related losses. Plaintiff
3 required and will continue to require healthcare and services. Plaintiff has incurred and will continue
4 to incur medical and related expenses. Plaintiff also have suffered and will continue to suffer mental
5 anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished
6 quality of life, increased risk of premature death, aggravation of preexisting conditions and activation
7 of latent conditions, and other losses and damages. Plaintiff also incurred direct medical losses and
8 costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
9 Plaintiff has also suffered loss of wages.

10 109. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
11 deliberate disregard for the value of human life and the rights and safety of consumers, including
12 Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and
13 deter them from similar conduct in the future.

14 110. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory
15 damages and punitive and exemplary damages together with interest, the costs of suit and attorneys'
16 fees, and such other and further relief as this Court deems just and proper.

17 **FIFTH CLAIM FOR RELIEF**

18 **Fraudulent Misrepresentation & Concealment**

19 111. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully
20 set forth herein and further allege as follows.

21 112. Defendants' superior knowledge and expertise, their relationship of trust and
22 confidence with doctors and the public, their specific knowledge regarding the risks and dangers of
23 BEXTRA, and their intentional dissemination of promotional and marketing information about
24 BEXTRA for the purpose of maximizing its sales, each gave rise to the affirmative duty to
25 meaningfully disclose and provide all material information about BEXTRA's risks and harms to
26 doctors and consumers.

27 113. Defendants made fraudulent affirmative misrepresentations with respect to BEXTRA in
28 the following particulars:

1 a. Defendants represented through their labeling, advertising, marketing materials,
2 detail persons, seminar presentations, publications, notice letters, and regulatory submissions that
3 BEXTRA had been tested and found to be safe and effective for the treatment of pain and
4 inflammation; and

5 b. Defendants represented that BEXTRA was safer than other alternative
6 medications.

7 114. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or
8 recklessly concealed material adverse information regarding the safety and effectiveness of BEXTRA.

9 115. Defendants made these misrepresentations and actively concealed adverse information
10 at a time when Defendants knew or had reason to know that BEXTRA had defects and was
11 unreasonably dangerous and was not what Defendants had represented to the medical community, the
12 FDA and the consuming public, including Plaintiff.

13 116. Defendants omitted, suppressed and/or concealed material facts concerning the dangers
14 and risk of injuries associated with the use of BEXTRA including, but not limited to, the
15 cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was
16 willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of
17 the risks associated with the use of BEXTRA in order to increase its sales.

18 117. The representations and concealment were undertaken by Defendants with an intent
19 that doctors and patients, including Plaintiff, rely upon them.

20 118. Defendants' representations and concealments were undertaken with the intent of
21 defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and
22 encourage the sale of BEXTRA.

23 119. Defendants' fraudulent representations evinced their callous, reckless, willful, and
24 depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

25 120. Plaintiffs' physician and Plaintiff relied on and were induced by Defendants'
26 misrepresentations, omissions, and/or active concealment of the dangers of BEXTRA in selecting
27 BEXTRA treatment.

28 121. Plaintiff and the treating medical community did not know that the representations were

1 false and were justified in relying upon Defendants' representations.

2 122. Had Plaintiff been aware of the increased risk of side effects associated with BEXTRA
3 and the relative efficacy of BEXTRA compared with other readily available medications, Plaintiff
4 would not have taken BEXTRA as she did.

5 123. As a direct and proximate consequence of Defendants' acts, omissions, and
6 misrepresentations described herein, Plaintiff sustained serious injuries and related losses. Plaintiff
7 required and will continue to require healthcare and services. Plaintiff has incurred and will continue
8 to incur medical and related expenses. Plaintiff also have suffered and will continue to suffer mental
9 anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished
10 quality of life, increased risk of premature death, aggravation of preexisting conditions and activation
11 of latent conditions, and other losses and damages. Plaintiff also incurred direct medical losses and
12 costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
13 Plaintiff has also suffered loss of wages.

14 124. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
15 deliberate disregard for the value of human life and the rights and safety of consumers, including
16 Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and
17 deter them from similar conduct in the future.

18 125. WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory
19 damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys'
20 fees, and such other and further relief as this Court deems just and proper.

21 **SIXTH CLAIM FOR RELIEF**

22 **Unjust Enrichment**

23 126. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully
24 set forth herein and further allege as follows.

25 127. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or
26 suppliers of BEXTRA.

27 128. Plaintiff paid for BEXTRA for the purpose of managing their pain safely and
28 effectively.

129. Defendants have accepted payment from Plaintiff for the purchase of BEXTRA.

130. Plaintiff did not receive the safe and effective pharmaceutical product for which she paid.

131. It is inequitable and unjust for Defendants to retain this money because Plaintiff did not in fact receive the product Defendant represented BEXTRA to be.

132. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

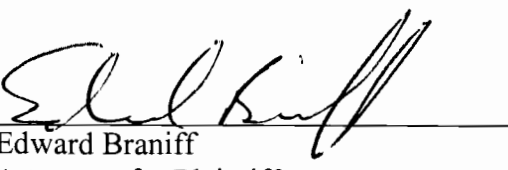
WHEREFORE, Plaintiff request the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Damages for loss of consortium, care, comfort, society and companionship in an amount within the jurisdiction of this Court and according to proof;
6. Punitive and exemplary damages;
7. Pre-judgment and post-judgment interest as provided by law;
8. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
9. Such other and further relief as the Court deems just and proper.

Dated: May 4, 2007

WEITZ & LUXENBERG, PC

By:


Edward Braniff
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: May 4, 2007

WEITZ & LUXENBERG, PC

By:



Edward Braniff
Attorneys for Plaintiff